5/4/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
TT5|M

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-39664

April 23, 1998

John Zonneveld
Zonneveld Dairies Inc.
1560 East Cerini
Laton, California 93242

WARNING LETTER

Dear Mr. Zonneveld:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on March 26 through 30, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On February 12, 1998, you consigned a dairy cow (identified by USDA laboratory report number 208302) to be slaughtered as human food. This cow which was delivered for introduction into interstate commerce by your firm was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of penicillin in the kidney at 1.20 parts per million (ppm), and in the liver at 0.06 ppm, and in the muscle at 0.09 ppm. The tolerance level for penicillin in the edible tissues of cattle has been established at 0.05 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

You are adulterating the drug Pen-Aqueous brand penicillin G procaine within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with its approved labeling. Penicillin G procaine labeling prescribes a dosage of 1 mL per 100 pounds of body weight and warns against using more than 10 mLs per injection site. Your practice of administering up to two 20 mL injections per day in one site in an animal results in a dosage in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur and is likely the cause of the illegal residues found in the animal you sold for slaughter.

Your use of the drug Dexasone brand dexamethasone solution is not in conformance with prescribed labeling directions. Labeling directions prescribed by your veterinarian specify that cows to which dexamethasone has been administered must be withheld for 72 hours from slaughter, and also prescribes a milk withdrawal for 72 hours. Treating lactating dairy cows with dexamethasone just prior to sending them to slaughter is not in accordance with prescribed labeling.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of February 20, 1989, through February 12, 1998, your firm sold ten cows which contained violative levels of penicillin, sulfadimethoxine, oxytetracycline, tetracycline, chlortetracycline, and neomycin. As a result of the violative residues, inspections were conducted of your dairy on August 7, 1989; March 26, 1991; September 6, 1991; October 21, 1992; September 26, 1995; and March 15, 1996. During each of the inspections you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. Two Warning Letters were issued to you, on June 26, 1991, and October 26, 1995, as a result of these inspections. Also, the U.S. Department of Agriculture has sent you letters for each of the cull cows and calves in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro
District Director
San Francisco District

cc: William H. Meyer, DVM
Kingsburg Veterinary Clinic
1991 Simpson Street
Kingsburg, California 93631